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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/617,456	07/11/2003	Mongkol Sriwongjanya	141-287	3239

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EXAMINER	
TRAN, SUSAN T	

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
10/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Supplemental Notice of Allowability	Application No. 10/617,456	Applicant(s) SRIWONGJANYA ET AL.	
	Examiner Susan T. Tran	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *Amendment filed 06/14/07*.

2. ☒ The allowed claim(s) is/are *12-16,19,25-28,32,35-49,51-55 and 59-64*.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

SUPPLEMENTAL EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Nicholas P. Chiara on 08/30/07.

The application has been amended as follows:

Claims 1, 3-11, *17, 18*, 21, 23, 24, 29-31, 33, 34 and 56-58 have been cancelled.

Claim 49 has been amended to read as follow:

--"A controlled release pellet consisting essentially of:

a) an inert core that is water swellable;

b) a drug layer applied to the inert core comprising:

i) metoprolol succinate;

ii) a binder; and

iii) optionally a surfactant;

c) a controlled release coating surrounding the drug layer comprising:

i) 75-90% of a water insoluble film forming polymer selected from the group consisting of cellulose acetate, cellulose acetate butyrate, ethyl cellulose, hydroxypropyl cellulose acetate, hydroxypropyl methyl phthalate and cellulose acetate phthalate or mixtures thereof;

ii) 2-10% of a channeling agent comprising methacrylic acid copolymer; and

iii) 5-15% of an emulsifier;

wherein said pellet exhibits the following dissolution profile when tested in a USP Type 2 apparatus at 75 rpm and 37°C in a phosphate buffer with a pH of 7.5,

0-40% of the metoprolol succinate is released after 2 hours;

5-50% of the metoprolol succinate is released after 4 hours;

25-80% of the metoprolol succinate is released after 8 hours;

not less than 50% of the metoprolol succinate is released after 16 hours."--

Claim 12, line 1, the phrase "in Claim 1" has been amended to "in Claim 49".

Claim 14, line 1, the phrase "in Claim 1" has been amended to "in Claim 49".

Claim 19, line 1, the phrase "in Claim 18" has been amended to "in Claim 49".

Claim 25, line 1, the phrase "in Claim 24" has been amended to "in Claim 49".

Claim 26, line 1, the phrase "in Claim 24" has been amended to "in Claim 49".

Claim 27, line 1, the phrase "in Claim 1" has been amended to "in Claim 49".

Claim 32, line 1, the phrase "in Claim 1" has been amended to "in Claim 49".

Claim 35, line 1, the phrase "in Claim 33" has been amended to "in Claim 62".

Claim 36, line 1, the phrase "in Claim 33" has been amended to "in Claim 35".

Claim 37, line 1, the phrase "in Claim 34" has been amended to "in Claim 63".

Claim 39, line 1, the phrase "in Claim 33" has been amended to "in Claim 62".

Claim 41, line 1, the phrase "in Claim 34" has been amended to "in Claim 63".

Claim 43, line 1, the phrase "in Claim 33" has been amended to "in Claim 62".

Claim 46, line 1, the phrase "in Claim 34" has been amended to "in Claim 63".

Claim 60, line 1, the phrase "in Claim 50" has been amended to "in Claim 49".

Claim 61, line 1, the phrase "in Claim 50" has been amended to "in Claim 49".

Claim 64 has been amended to read as follow:

--"A process for preparing a controlled release pellet consisting essentially of:

a) dissolving or suspending metoprolol succinate in an aqueous medium;

b) applying the aqueous medium with the dissolved or suspended metoprolol succinate onto a water swellable inert core to create a drug layer on the inert core; and

c) applying a controlled release coating to the drug layer, wherein the controlled release coating layer comprises:

i) 75-90% of a water insoluble film forming polymer selected from the group consisting of cellulose acetate, cellulose acetate butyrate, ethyl cellulose, hydroxypropyl cellulose acetate, hydroxypropyl methyl phthalate and cellulose acetate phthalate or mixtures thereof;

ii) 2-10% of a channeling agent comprising methacrylic acid copolymer; and

iii) 5-15% of an emulsifier;

and wherein said pellet exhibits the following dissolution profile when tested in a USP Type 2 apparatus at 75 rpm and 37°C in a phosphate buffer with a pH of 7.5,

0-40% of the metoprolol succinate is released after 2 hours;

5-50% of the metoprolol succinate is released after 4 hours;

25-80% of the metoprolol succinate is released after 8 hours;

not less than 50% of the metoprolol succinate is released after 16 hours."--

The following is an examiner's statement of reasons for allowance:

The closest prior art, Stark et al., teach a controlled release formulation comprising an inert core coated with active drug in the present of binder and other additives (column 3, lines 45-56). The active core is coated with a polymeric coating layer. Stark et al., however, do not teach the claimed drug, namely, metoprolol succinate having different solubility from the drug disclosed by Stark. Stark further does not teach the claimed coating composition that comprises specific water insoluble polymer, specific channeling agent, and an emulsifier, all in specific amounts. The combination of water-insoluble polymer and methacrylic acid copolymer as a channeling agent in specific amounts results in a release profile that is different from the release profile taught in Stark.

The rejections by Chen et al. are withdrawn in view of applicant's commonly own statement (see Remarks page 11, and Declarations filed 06/14/07).

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Claims 12-16, 19, 25-28, 32, 35-49, 51-55 and 59-64 are allowed.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SUSAN TRAN
PRIMARY EXAMINER

Art Unit 1615